

JAN 10 1997

K964274

510(k) Summary of Safety and Effectiveness

The following summary is submitted pursuant to 21 CFR 807.92:

Submitter: ComView
Date Prepared: October 21, 1996
Trade/Proprietary Name: WriteStar and ViewStar
Common/Usual Name: Digital image archival and review station.
Classification: Class II, 90JAA
Classification Name: None assigned; RE: HHS Publication FDA 91-4246
Panel: Radiology
Performance Standard: Voluntary; DICOM for digital exchange media.
Reason for 510(k): New product equivalency.
Predicate Devices:

Legally marketed predicate devices with the same intended use include the a) Digital Disk Recorder (DDR) or the Digital ViewStation with Dual Path Archiver manufactured by Eigen (RE: K942264); b) the Video Plus System with Analytical Workstation manufactured by Camtronics (RE: K941979); and c) the AccuLupe digital image archival and review station (RE: K955184).

Description:

The WriteStar is an independent computerized system used in the cardiac catheterization laboratories for managing, displaying, and analyzing digitized x-ray images. It has the following major components(minimally):

- ⇒ IBM compatible 486/586/ or Pentium computer.
- ⇒ A SVGA monitor
- ⇒ HP compatible laser jet printer.
- ⇒ CD-ROM/CD-R disk
- ⇒ Software program developed by ComView to run on the IBM OS/2 V3.0 or higher platform.

The archival/review is designed as an accessory to legally marketed medical devices that can digitize x-ray images in the cardiac cath lab. The WriteStar provides image digitization, archival, display, and exchange media compliant to the DICOM standard. The ViewStar provides image review and analysis capabilities and retrieval of data from CD-R disc.

The following questions have been addressed:

Is the device life supporting or life sustaining?	No
Is the device implanted?	No
Does the device design use software?	Yes
Level of concern for software (if applicable)?	Minor
Is the device sterile?	No
Is the device for single use?	No
Is the device for home use or prescription use?	No
Does the device contain drugs or biological products as a component?	No
Is the device a diagnostic Kit?	No

Intended Use

The WriteStar is designed to create convenient and efficient storage, display, and analysis of digital images of heart catheterization and other coronary procedures involving cine-film applications. The WriteStar is designed to support the cine-less cath lab environment and is meant to replace 35mm cine film, and cine projectors currently being used by the majority of cardiac catheterization laboratories. Cine film is currently being used as the permanent archival media for images acquired during heart catheterization. The WriteStar is able to function as an independent unit that accepts images from any imaging system an RS-170 video source.

The ViewStar is a review station. The ViewStar does not have the WriteStar's capability to record to a CD-R disk. The ViewStar can only read (view) a case study from a DICOM compliant CD-R disk.

The ViewStar/Write Star is able to review patient images from A CD-R disk that was previously recorded from an imaging device that uses the DICOM standard. The patient images are transferred from the CD-R disk to the internal hard disk of the WriteStar. Once the images are on the hard disk, the Cardiologist, or other qualified personnel, has the same means to review and analyze images. Analysis is provided via 3rd party industry standard software.

The WriteStar interfaces with commercially available devices that digitize and/or process cine images and or fluoro images and records these images on a 2GB or 4GB SCSI hard drives. These images are simultaneously displayed on the system console for image quality verification.

Images are acquired from the source device via RS-170 interface. The images are then displayed for review and analysis similar to a cine film projector. As in the cine film projector, the WriteStar will display cine images of a particular patient without the use of film.

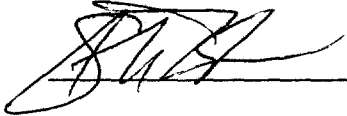
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Comparison of Predicate Devices

ComView, Inc.'s WriteStar performs the same functions, in the same environment, as the Camtronics' Archium, Eigen's Digital Disk Recorder Plus with DualPath Archiver, and E for M's AccuLupe. A comparison of device specifications and principles of operation indicates no new questions of efficacy, or substantial risk are raised.

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Signature:

A handwritten signature in black ink, appearing to read 'SM', is written over a horizontal line.

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